IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CIPLA LTD.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 15-424-LPS
	:	
SUNOVION PHARMACEUTICALS INC.,	:	
	:	
Defendant.	:	
	:	

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MEMORANDUM OPINION

June 27, 2017
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiff Cipla Ltd. ("Cipla") brought this patent infringement suit against Defendant Sunovion Pharmaceuticals, Inc. ("Sunovion"), alleging that Sunovion's Xopenex HFA® aerosol inhaler infringes Cipla's U.S. Reissued Patent No. RE43,984 (the "'984 Reissue"). The asserted patent describes and claims optically pure salbutamol salts of tartaric acid obtained by resolving a racemic or otherwise optically impure mixture of salbutamol enantiomers with tartaric acid. Presently before the Court is the issue of claim construction. The parties submitted technology tutorials (*see* D.I. 89, 93), claim construction briefs (*see* D.I. 90, 94, 119, 146, 149), and expert declarations (*see* D.I. 92, 96, 135-137). The Court held a claim construction hearing on May 1, 2017, at which both sides presented oral argument and expert testimony. (*See* D.I. 233 ("Tr."))

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application."

Id. at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . ." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope

using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, "the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to

establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERMS

A. "Levalbuterol L-tartrate"[1] "(R)-salbutamol-(L)-tartrate salt"[2]

Cipla "R-salbutamol salt of L-tartaric acid"
Sunovion "A 1:1 ratio of (R)-salbutamol cation and L-bitartrate monoanion"[3]
Court "R-salbutamol salt of L-tartaric acid"

The parties dispute whether the prosecution histories of the '984 Reissue and related Cipla patents, which Sunovion characterizes as containing a "long line of disclaimers" (D.I. 149 at 13), limit the scope of these terms to levalbuterol L-**Bi**tartrate, the salt with a 1:1 ratio of levalbuterol cation and L-bitartrate monoanion. In Sunovion's view, "Cipla surrendered any patent coverage to a tartrate salt made by using less than 1.0 mole equivalent of tartaric acid," and thereby surrendered any coverage over the 2:1 variant of the compound, levalbuterol **hemi**tartrate. (*Id.*)

The Court finds that there is no "unambiguous disavowal that clearly and unmistakably disclaims the plain meaning" of these claim terms. *Biogen Idec, Inc. v. GlaxoSmithKline LLC*,

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[1]This term appears in claims 9 and 10 of the '984 Reissue.

[2]This term appears in claims 17 and 18 of the '984 Reissue. The parties agree that Levalbuterol is another name for R-(–)-salbutamol, the compound's levorotatory enantiomer. (*See, e.g.*, D.I. 84-1 at 1 ("Levalbuterol L-tartrate . . . is also known as R-salbutamol L-tartrate"))

[3]Sunovion asks the Court to construe these same terms as they appear in Sunovion's U.S. Patent No. 7,256,310 (the "'310 patent") – which is ***not*** asserted in this case – as "[a] **2:1** ratio of (R)-salbutamol cation and L-tartrate dianion." (D.I. 110-1 at 2 of 80 (emphasis added)) The Court is not persuaded it is necessary or appropriate to do so.

713 F.3d 1090, 1098 (Fed. Cir. 2013) (internal quotation marks omitted).

Cipla, pointing to product labels and expert testimony, argues that "skilled artisans use the term 'tartrate' to refer to ***both*** the 2:1 salt and the 1:1 salt." (D.I. 146 at 2 (citing D.I. 136 ¶¶ 16-25)) The Court agrees that the "ordinary and customary " meaning of "Levalbuterol L-tartrate" includes both the 2:1 and 1:1 forms. (*See generally* D.I. 147 Ex. A at 58-60 (Sunovion expert testifying "there has been enormous sloppiness in the way in which the term 'tartrate' is used"))

Sunovion's principal contention is that Cipla made "repeated, clear, and unmistakable" disclaimers in the prosecution histories by emphasizing use of a molar excess of tartaric acid to salbutamol. (D.I. 149 at 16; *see generally id.* at 11-13, Table 1) To Sunovion, then, Cipla "emphasized molar excess so many times and specifically disparaged the use of a molar deficiency" that these claim terms "cannot be construed to . . . include salts made by both a molar excess ***and*** a molar deficiency," and therefore cannot cover both the 2:1 and 1:1 salts. (*Id.* at 15)[4]

[4]The great majority of Sunovion's references to the intrinsic record refer not to the '984 Reissue's prosecution history, but instead to the prosecution history of its parent patent, U.S. Patent No. 6,995,286 (the "'286 patent"), and of other related patents. (*See, e.g.*, D.I. 149 at 11-13, Table 1; D.I. 110-1 at 2-3) The '984 Reissue claims do not use the same claim terms as the claims of the '286 patent. Hence, Cipla directs the Court to cases holding that "although a parent patent's prosecution history may inform the claim construction of its descendant," the doctrine of prosecution history disclaimer "generally does not apply when the claim term in the descendant patent uses different language." *Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1182 (Fed. Cir. 2006) (internal quotation marks omitted); *see also Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1078 (Fed. Cir. 2005) ("[T]he prosecution of one claim term in a parent application will generally not limit different claim language in a continuation application."); *see also Regents of Univ. of Minnesota v. AGA Med. Corp.*, 717 F.3d 929, 943 n.8 (Fed. Cir. 2013) ("The sole exception is when the disclaimer is directed to the scope of the invention as a whole, not a particular claim."). In response, Sunovion relies on *Profoot, Inc. v. Merck & Co.*, 663 F. App'x 928, 933 (Fed. Cir. 2016) (*see* Tr. at 89-91, 135-37; D.I. 216), where the Federal Circuit observed that a parent patent's prosecution history "support[ed] the district court's construction" of a claim term in a descendant patent. But *Profoot* stated that it was not carrying forward any disclaimer that might appear in the parent's prosecution history, given the differing claim language. *Id.* at 933 n.2.

But the doctrine of prosecution history disclaimer does not permit the Court to narrow the ordinary meaning of a disputed claim term absent an "unambiguous disavowal[]," *Grober v. Mako Prods., Inc.*, 686 F.3d 1335, 1341 (Fed. Cir. 2012), and here Sunovion has identified no such unambiguous disavowal.

Sunovion's argument for finding a clear and unambiguous disclaimer essentially rests on it proving that, at the pertinent time, a person of ordinary skill in the art ("POSA") would have "***expect[ed]*** a 1:1 bitartrate salt to form from a resolution performed using a molar excess of tartaric acid to resolution substrate." (D.I. 149 at 2 (citing, *e.g.*, D.I. 96 ¶¶ 70-73; D.I. 137 ¶¶ 11-14; D.I. 150-1, Exs. A, B) (emphasis added)) But a general expectation is not enough. Chemistry is an often unpredictable art. *See Eisai Co. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008); *see also Sannofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1379 (Fed. Cir. 2006) (referring to the "unpredictability of salt formation"). Neither the expert testimony presented to the Court, nor the prosecution history, demonstrates that a POSA at the time of the invention would have expected that the starting ratio would have automatically and unavoidably produced a particular outcome. (*See, e.g.*, Tr. at 87 (Sunovion expert testifying that "[y]ou ***expect*** that using an excess, it's going to ***favor*** the one-to-one and ***disfavor*** the two-to-one") (emphasis added); *id.* at 106 (counsel for Sunovion acknowledging that beginning "with a molar deficiency . . . is not the be all and end all of the conversation"); *id.* at 115 (Cipla expert testifying that "one can[not] just base the product outcome [on] what the starting ratio is"); D.I. 147, Ex. A at 103 (Sunovion expert testifying that it is "possible to use [molar excess] and attain some of the 2:1 salt"); *see also generally* D.I. 146 at 5-6 (Cipla arguing persuasively, "[n]owhere in the prosecution history did the applicants indicate or imply that the starting ratio of the

salbutamol and tartaric acid dictates the ratio of salbutamol cation and tartrate anion in the salt that results from the process."))

Nor is the Court persuaded that the '984 Reissue's specification compels adoption of Sunovion's construction, even if Examples 1 and 6, along with Scheme A, apparently contemplate a 1:1 (bitartrate) output. (*See* D.I. 149 at 5-7 (citing and summarizing expert declaration and testimony))

Sunovion alternatively proposes a "compromise" construction that would read a process limitation into the claims, requiring that the compound be produced from a molar excess of tartaric acid, regardless of the resulting output. (*See* Tr. at 73) This argument largely rests on the same purported prosecution history disclaimer as Sunovion's preferred construction and, therefore, fares no better.

Sunovion also emphasizes the '984 Reissue applicant's response to an obviousness rejection over Deng, a prior art reference. There, Cipla told the Patent Office that, in contrast to Deng, "the claimed tartrate salts . . . were prepared using a ***molar excess of tartaric acid to salbutamol***." (D.I. 110-1 at A029-30) Cipla also represented that Deng "does not provide any reasonable motivation for a skilled artisan to use a molar excess of tartaric acid to salbutamol (which is against the teachings of Deng) because diastereoisomeric salt formation is unpredictable . . . and Deng teaches a molar excess of albuterol to the resolving agent(s)." (*Id.* at A030) Cipla was apparently seeking to distinguish Deng's use of "expensive" and single-use tartaric acid ***derivatives*** and its formation of an "inclusion complex." (*Id.*) Cipla's statements regarding its use of a molar excess appear to be tied to its explanations about the unpredictability of "diastereoisomeric salt formation." (*Id.* at A030-31) Hence, it is not "***clear*** that the process"

limitation Sunovion insists be included in the Court's construction is "an essential part of the claimed invention." *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1375 (Fed. Cir. 2007) (emphasis added).[5]

Thus, the Court will adopt Cipla's proposed construction of these claim terms.

B. "pure and isolated"[6]

Cipla "A tartrate salt that is substantially free of any impurities"
Sunovion "A resolution intermediate that is converted to (R) salbutamol substantially free of the (S) enantiomer that may further optionally be converted to a pharmaceutically acceptable salt of (R) salbutamol"
Court "A tartrate salt that is substantially free of any impurities"

Sunovion, again pointing to the prosecution history, contends that Cipla is "estopped from attempting to extend its claims to any salt that is not used as an intermediate in a resolution method." (D.I. 94 at 15 (emphasis omitted)) Cipla responds that the '984 Reissue "was filed for the purpose of obtaining product claims, as compared to the process claims of the original patent," and that Sunovion "impermissibly seek[s] to import process limitations into these product claims." (D.I. 90 at 1) The Court agrees with Cipla that this claim term does not exclude final products from the scope of the asserted claims.

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[5]Sunovion contends that the Court's adoption of Cipla's construction "would cause Cipla to violate the rule of recapture." (D.I. 149 at 17 n.5) Generally, "[w]hether . . . broadened claims are invalidated by the recapture rule is an issue separate from construction." *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1332 (Fed. Cir. 2007). The instant case is not one in which "available techniques of construction yield two possible interpretations of a reissue claim, only one of which includes previously surrendered matter." *Id.* at 1332 n.3.

[6]This term appears in all asserted claims (9, 10, 17, and 18) of the '984 Reissue.

Cipla admits that it referred to its claimed salts as "intermediates" during prosecution. (*See* D.I. 146 at 11-12; *see also* D.I. 110-1 at A052-53) But the applicant did not clearly and unmistakably rely on that characterization in distinguishing Deng. (*See generally* D.I. 149 at 19-20 (quoting D.I. 90 at 11)) When Cipla amended its claims to introduce the "pure and isolated" language, it explicitly represented to the examiner that it was doing so to address the "concern . . . that optically pure (R)-salbutamol-(L)-tartrate salt and (S)-salbutamol-(D)-tartrate salts could be inherently present in the resolution mixtures of Deng even if they . . . cannot be isolated in pure form." (D.I. 110-1 at A053)

Sunovion points to a later amendment in which Cipla again distinguished Deng on the basis that "Deng fails to teach or suggest . . . isolation of an (R)-salbutamol-L-tartrate salt as an intermediate to making optically pure (R)-salbutamol." (D.I. 94 at 8 (quoting D.I. 110-1 at A070)) Having considered the full context, the Court is not persuaded that there was a clear and unmistakable disavowal of claim scope. (*See, e.g.*, D.I. 110-1 at A071 ("Deng clearly states a preference for choosing a particular resolving agent (*i.e.*, D- for (*R*)-salbutamol and L- for (*S*)-salbutamol), and that preference is diametrically opposed to what is disclosed in the present application."); '984 Reissue at 8:56-59)

In sum, the Court does not view Cipla's references to its salts as intermediates as a clear and unmistakable disavowal with any relationship to the term "pure and isolated." Accordingly, the Court will adopt Cipla's proposed construction.

C. "in crystalline form"[7]

Cipla Plain and ordinary meaning or "Having the structure of a crystal"
Sunovion Plain and ordinary meaning (in the '984 Reissue) and Having the structure of a crystal as specified therein (in the '310 patent)
Court "having the structure of a crystal"

Sunovion contends that "no structure of any crystal was ever described in the '984 Reissue or related prosecution history" and that a person of ordinary skill in the art would understand "any crystalline form claimed in the '984 Reissue to refer to a crystalline form of a 1:1 bitartrate salt," in contrast to Sunovion's '310 patent. (D.I. 149 at 21-22) Claim 10 of the '984 Reissue was copied from the '310 patent, but the Patent Office did not declare an interference. (*See* D.I. 110-1 at A001-02)

The Court has already rejected Sunovion's attempt to limit the scope of the asserted claims to 1:1 bitartrate salts. The Court further agrees with Cipla that "crystalline form" is a known term in the art; the '984 Reissue's specification refers to tartrate salt "crystals" and crystallization. (*E.g.*, '984 Reissue at 6:35, 7:31) Construction of this term as used in the '984 Reissue is not controlled by how the term is used in Sunovion's '310 patent. Although Cipla proposed an interference proceeding, no interference was ever declared. (*See generally* D.I. 110-1 at A001-09)

[7]This term appears in claim 10 of the '984 Reissue.

Accordingly, the Court will adopt Cipla's proposed construction.

D. "pharmaceutically acceptable salt"[8]

Cipla No construction required
Sunovion "A final product of the originally claimed processes, excluding an intermediate of a levalbuterol salt, that is formed after a conversion step"
Court No construction

Because this term does not appear in any claim of the '984 Reissue, the Court declines to construe it. The Court is not persuaded by Sunovion's insistence that construction is required; instead, construction of this term does not appear to be necessary to resolve any dispute between the parties.

III. CONCLUSION

The Court construes the disputed terms as explained above. An appropriate Order follows.

[8]This term appeared in original claim 8, which "forms no part of" the '984 Reissue. (*See* '984 Reissue at 1:5-9; 8:16-19)